UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

MARCIA SABOL,

Plaintiff,

- against -

BAYER HEALTHCARE PHARM., INC., et al.,

Defendants.

18 Civ. 11169 (VM)

DECISION AND ORDER

VICTOR MARRERO, United States District Judge.

Plaintiff Marcia Sabol ("Sabol") brings this action against defendants Bayer HealthCare Pharmaceuticals, Inc., Bayer Corporation, and Bayer Healthcare LLC (together, "Bayer"); Bracco Diagnostics, Inc. ("Bracco"); and GE Healthcare Inc. ("GEHC") and General Electric Company ("GE Co.," and together with GEHC, "GE") (collectively, "Defendants").[1] Sabol brings two causes of action in her amended complaint: strict product liability under a failure to warn theory, and negligence. (See "Amended Complaint," Dkt. No. 64 ¶¶ 124-69.)

Before the Court are the pre-motion letters submitted by Defendants seeking leave to file a motion to dismiss the Amended Complaint. The Court construes such letters as

[1] Sabol also named McKesson Corporation as a defendant. The parties stipulated to a voluntary dismissal of Sabol's claims against McKesson Corporation pursuant to Fed. R. Civ. P. 41(a)(1)(A)(ii) on October 23, 2019. (See Dkt. No. 79.)

motions to dismiss the Amended Complaint[2] pursuant to Rule 12(b)(2), (3) and (6) of the Federal Rules of Civil Procedure ("Rule 12(b)(2)," "Rule 12(b)(3)," and "Rule 12(b)(6)") (the "Bayer Motion," the "Bracco Motion," and the "GE Motion") (collectively, the "Motions"). For the reasons set forth below, the Motions are GRANTED in part and DENIED as moot in part.

I. BACKGROUND[3]

Gadolinium, a heavy metal, is a type of contrast agent. Contrast agents are injected into the body before an MRI procedure to enhance the imaging. Between May 2007 and July 2015 Sabol underwent twenty-three MRIs, and before each MRI a technician injected her with one of Defendants' gadolinium-based contrast agents: Magnevist (made by Bayer), MultiHance (made by Bracco), or Omniscan (made by GE) (the "Contrast Agents"). Gadolinium is toxic, but the Contrast Agents are intended to "pass[] through and eventually [be] eliminated from the body, mainly by the kidneys, after the MRI." (Amended Complaint ¶ 46.)

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[2] Kapitalforeningen Lægernes Invest v. United Techs. Corp., 779 F. App'x 69, 70 (2d Cir. 2019) (Mem.) (affirming district court ruling deeming exchange of letters as motion to dismiss).

[3] Except as otherwise noted, the factual background below derives from the Amended Complaint and the facts there pleaded, which the Court accepts as true for the purposes of ruling on a motion to dismiss. See infra Part II. Except where specifically quoted, no further citation will be made in Part I to the Amended Complaint.

Sabol filed her lawsuit on November 30, 2018, alleging that the Contrast Agents did not, as intended, pass through her body, but rather were retained, causing serious injuries. (See "Complaint," Dkt. No. 1.) She alleges that gadolinium remains permanently in key organs, bones, and skin, causing fibrosis and the following symptoms, among others: "cognitive impairment, pain, impaired mobility, bone and joint pain, muscle pain, numbing sensation in extremities, burning sensation, depression, and anxiety." (Amended Complaint ¶ 4.) Her suit rests on the contention that, after the FDA approved the Contrast Agents, the manufacturers learned additional information about the risks of gadolinium retention that they should have disseminated. Sabol faults the Defendants for issuing warnings about the Contrast Agents only to patients with chronic, severe kidney disease or acute kidney injury and not warning that Contrast Agents may be retained even by patients with normal kidney function. The Amended Complaint brings causes of action against all Defendants for (1) strict product liability (failure to warn) and (2) negligence.

1. Bayer's Motion to Dismiss

Consistent with the Court's Individual Practices, Bayer and Sabol exchanged letters regarding Bayer's anticipated motion to dismiss the Complaint.

By letter dated February 25, 2019, Bayer argued that the Complaint should be dismissed for three reasons. (See "Bayer February 25 Letter," Dkt. No. 44.) Bayer's first argument for dismissal is that the Court lacks personal jurisdiction over it. Bayer notes that New York is not its place of incorporation or principal place of business; furthermore, Sabol does not allege Bayer did anything more than develop Magnevist, which then reached New York through the nationwide stream of commerce. (See id. at 1-2.) Bayer next argues that, for similar reasons, the Southern District of New York is an improper venue. (See id. at 2.) Bayer's third contention is that the Complaint fails to state a claim because "gadolinium retention" is not a legally cognizable injury, and Sabol's other alleged injuries -- "fibrosis" and "related injuries" -- are preempted by Magnevist's FDA-approved label. (See id. at 2-3.) Similarly, Bayer states that Sabol's injuries were not foreseeable, because neither the FDA nor the medical community recognize fibrosis as a side effect of Magnevist in individuals who, like Sabol, have normal kidney function. (See id. at 3.)

By letter dated March 4, 2019, Sabol responded to Bayer's February 25 Letter. (See "March 4 Letter to Bayer," Dkt. No. 48.) Sabol argues that the Complaint makes out a prima facie

showing of personal jurisdiction because she alleges that she was injected with the Contrast Agents in New York and also that Bayer has had significant contact with the state. (See id. at 1-2.) Next, in support of her contention that the Complaint states a claim for relief, Sabol argues first that the Complaint adequately alleges that she was physically, mentally, and economically damaged as a result of Bayer's conduct (see id. at 2); second, that Bayer did, in fact, acquire new information about Magnevist post-FDA approval sufficient to allow it to amend the label, meaning that her claims are not preempted (see id. at 3); and third, that in light of the information Bayer acquired about Magnevist, her injuries were foreseeable (see id.).

By letter dated April 5, 2019, Bayer informed the Court that the parties had been unable to resolve their dispute. ("Bayer April 5 Letter," Dkt. No. 57.) Following a telephone conference (see "May 30 Conference," Dkt. Minute Entry for May 30, 2019), Sabol filed the Amended Complaint on July 15, 2019.

By letter dated July 29, 2019, Bayer reasserted two of the three arguments it first made in its February 25 Letter. ("Bayer July 29 Letter," Dkt. No. 65.) While Bayer no longer argues that it is not subject to personal jurisdiction in

this Court, Bayer continues to assert that venue is not proper in the Southern District of New York (id. at 1), and further argues that the Amended Complaint fails to state a claim because Sabol's claims are preempted, she fails to show that her alleged injuries were foreseeable, and she acknowledges that gadolinium retention is not a cognizable injury. (Id. at 2-3.)

By letter dated July 31, 2019, Sabol responded to the Bayer July 29 Letter. ("July 31 Letter to Bayer," Dkt. No. 70.) Sabol first contends that because a substantial part of the events occurred in New York, the allegations in the Amended Complaint easily meet the test for venue set forth in Neufeld v. Neufeld, 910 F. Supp. 977, 986 (S.D.N.Y. 1996). Sabol also responds to Bayer's arguments that the Amended Complaint fails to state a claim. She maintains that her claims are not preempted because the Amended Complaint cites "a great deal" of newly acquired information that should have led Bayer to change its label. (Id. at 2.) Last, she states that fibrosis caused by gadolinium retention is a legally cognizable and foreseeable injury. (Id. at 3.)

By letter dated August 30, 2019, Bayer responded to Sabol's July 31 Letter. (See "Bayer August 30 Letter," Dkt. No. 81.) Bayer argues first that the Southern District of New

York is not a proper venue because not all defendants are residents there, and because Sabol does not allege that the events or omissions giving rise to the claim occurred in the Southern District. Furthermore, Bayer notes that Sabol does not allege that there is no district in which the action could be brought, such that venue is proper in any district in which any defendant is subject to personal jurisdiction. (Bayer August 30 Letter at 1-2.) Bayer next states that Sabol's claims are preempted because she did not demonstrate any scientific development showing reasonable evidence of a causal connection between her claimed injuries and the use of Magnevist in patients with normal kidney function. Similarly, Bayer disputes that Sabol's injuries were reasonably foreseeable or that gadolinium retention is a legally cognizable injury. (Id. at 3.)

By letter dated September 4, 2019, Sabol responded to the Bayer August 30 Letter. (See "September 4 Letter," Dkt. No. 82.) Sabol argues that venue is proper in the Southern District of New York because a substantial part of the events -- fourteen out of the twenty-three injections -- occurred at Mount Sinai Medical Center in Manhattan, within the Southern District of New York. Furthermore, Sabol argues, venue is proper in the Southern District because defendant GE Co. is

a New York company. Second, Sabol argues that her claims are not preempted because the evidence cited in the Amended Complaint demonstrates that people with normal renal function suffer from gadolinium retention and that gadolinium retention causes physical injuries. She also argues that she has sufficiently alleged that her injuries were foreseeable, and that she has pled a legally cognizable injury. (Id. at 3 (citing Amended Complaint ¶¶ 4, 147).)

2. GE's Motion to Dismiss

By letter dated February 25, 2019, GE requested a pre-motion conference with regard to its anticipated motion to dismiss the complaint as to GE for failure to state a claim. (See "GE February 25 Letter," Dkt. No. 42.) GE advances two arguments why the Complaint should be dismissed for failure to state a claim. First, GE argues that Sabol's claims are conclusory and do not detail how GE breached its duty of care, how Omniscan was marketed to Sabol, what Sabol's healthcare providers told her about Omniscan, or what risks she knew about. (See id. at 2.) Second, GE contends that Sabol fails to allege causation. As to general causation, GE argues that she fails to allege that gadolinium retention places her at risk of any disease. (See id.) Indeed, GE writes, the FDA has rejected the premise of any association -- let alone any

causal link -- between gadolinium retention and any disease. (See id. at 3.) As to specific causation, GE asserts that Sabol fails to allege that gadolinium retention caused her any actual injury, objective medical symptoms, or medical diagnosis. (See id.) Further, GE argues in the alternative that the learned intermediary doctrine bars Sabol's claims because she fails to allege that her physician would have prescribed a different product than Omniscan if he had been provided an alternative warning. (See id.)

By letter dated March 4, 2019, Sabol outlined the reasons why she believes a motion to dismiss would not succeed. (See "March 4 Letter to GE," Dkt. No. 50.) First, Sabol argues that the Complaint adequately alleges that she was physically, mentally, and economically damaged, and that her injuries (fibrosis caused by gadolinium retention) are a direct result of GE's conduct. (See id. at 2.) Second, Sabol argues that, in light of information GE acquired about Omniscan after FDA approval, her injuries were, in fact, foreseeable. (See id.) Third, Sabol argues that the Complaint adequately alleges causation, because she alleges that gadolinium retention caused her fibrosis, which is on the same continuum as nephrogenic systemic fibrosis. (See id.) Sabol notes that several jurisdictions outside the United

States have banned or restricted the use of the Contrast Agents. (See id. at 2-3.)

By letter dated April 1, 2019, GE informed the Court that its letter exchange with Sabol yielded no progress and formally requested a pre-motion conference. (See "GE April 1 Letter," Dkt. No. 56.) Sabol filed the Amended Complaint, and by letter dated July 29, 2019 GE outlined its arguments for why amendment did not cure the deficiencies in the Complaint. (See "GE July 29 Letter," Dkt. No. 66.) First, with respect to defendant GEHC, GE argues that GEHC is not subject to the Court's general jurisdiction because it is neither headquartered nor incorporated in New York, nor do the claims arise from its contacts with the forum such that specific jurisdiction would be appropriate. (Id. at 1-2.) Second, GE writes that Sabol fails to state a claim against GE Co. because GE Co. is a distinct legal entity that was not involved in manufacturing Omniscan, and even if it were, Sabol's alleged injuries are not foreseeable or cognizable. (Id. at 2-3.) Third, GE contends that Sabol's claims are preempted, especially because her only administrations of Omniscan occurred in 2008, years before the first published research cited in the Amended Complaint regarding gadolinium retention in patients with normal renal function. (Id. at 3.)

By letter dated August 5, 2019, Sabol responded to GE's July 29 Letter. (See "August 5 Letter," Dkt. No. 72.) Sabol first states that the Court has jurisdiction over GEHC because GEHC actively marketed and distributed Omniscan to New York hospitals and her claim arises out of GEHC's forum-related activities. Sabol further alleges that GEHC is a wholly owned subsidiary of GE Co., which is a New York company. (Id. at 1-2.) With respect to her claims against GE Co., Sabol maintains that her claim is legally cognizable because her Amended Complaint contains sufficient allegations of the damages she suffered as a result of GE's conduct. Similarly, she contends that she sufficiently alleged that her injuries were foreseeable because the Amended Complaint contains the allegation that her injuries were foreseeable and could have been prevented by Defendants. (Id. at 2.) Last, Sabol asserts that her claims are not preempted because the Amended Complaint cites to studies that demonstrate that in people with normal renal function, gadolinium retention causes a variety of physical injuries and impairments. (Id. at 2-3.)

By letter dated September 11, 2019, GE responded to the August 5 Letter. (See "GE September 11 Letter," Dkt. No. 74.) GE points out that since Sabol only received injections of Omniscan in Florida, not New York, the fact that she lived in

New York at the time of the other injections does not confer specific jurisdiction over GEHC in New York. (GE September 11 Letter at 1-2.) GE also argues that Sabol's claims against GE Co. must be dismissed because the parent-subsidiary relationship is not sufficient, without more, to make the parent liable for the acts of the subsidiary. (Id. at 3.) Finally, GE reiterates its argument that Sabol's claims against it are preempted because the Amended Complaint does not allege that GE had any newly acquired information in 2008, when Sabol received Omniscan injections, that would have permitted it to change Omniscan's label. (Id.)

By letter dated September 13, 2019, Sabol responded to the September 11 Letter. (See "September 13 Letter," Dkt. No. 83.) Sabol argues that the Court may exercise jurisdiction over GEHC because GEHC purposefully availed itself of the benefits and protections of New York law, and her claim arises out of those activities. Sabol also argues that she was required to join GEHC under Fed. R. Civ. P. 19(a)(1)(A), which provides that a party must be joined if, in that party's absence, the court could not accord complete relief among existing parties. Sabol further requests jurisdictional discovery in the event the Court doubts it has jurisdiction over GE. Sabol next argues that she has stated a claim against

GE Co. because GEHC is a wholly owned subsidiary and the Omniscan label states that it is trademarked by "General Electric Company or one of its subsidiaries." (September 13 Letter at 2.) Sabol also requests the opportunity to conduct discovery to better specify GE's actions. Lastly, Sabol argues that her claim is not preempted because the Amended Complaint alleges that studies and reports show that people with normal renal function suffer from gadolinium retention, which in turn causes a variety of physical injuries and impairments. (Id. at 2-3.)

3. Bracco's Motion to Dismiss

By letter dated July 29, 2019, Bracco requested a conference regarding its proposed motion to dismiss the Amended Complaint. (See "Bracco July 29 Letter," Dkt. No. 68.) Bracco makes two arguments in favor of dismissal. First, Bracco submits that it is not subject to the Court's specific jurisdiction because Sabol received MultiHance injections only in Florida, and Bracco is not subject to the Court's general jurisdiction because it is a Delaware corporation with its principal place of business in New Jersey. (Id. at 1.) Second, by incorporating the arguments made by Bayer, Bracco argues that Sabol's claims are preempted and that her Amended Complaint fails to state a claim that her injuries

were reasonably foreseeable or that her injuries were caused by Bracco's failure to warn her of the risks associated with gadolinium retention. (Id. at 2.)

By letter dated July 31, 2019, Sabol responded to the Bracco July 29 Letter. (See "July 31 Letter to Bracco," Dkt. No. 69.) Sabol states that the Court may exercise personal jurisdiction over Bracco because she sufficiently alleged that Bracco purposefully availed itself of the benefits and protections of New York law and marketed and distributed MultiHance to facilities in New York. Furthermore, she notes that she was required to join Bracco under Fed. R. Civ. P. 19(a)(1)(A). (July 31 Letter to Bracco at 1.) Sabol next argues that the Amended Complaint sufficiently states a claim for negligence and strict liability, and that her claim is not preempted because she cites studies demonstrating that gadolinium retention can cause injuries in people with normal renal function. (Id. at 1-2.) Sabol further contends that the Amended Complaint sufficiently alleges foreseeability, because it includes the allegation that her injuries were foreseeable. (Id. at 3.)

By letter dated September 10, 2019, Bracco responded to the July 31 Letter. (See "Bracco September 10 Letter," Dkt. No. 80.) Bracco informed the Court that its letter exchange

with Sabol had not resolved the dispute. Bracco reiterates that its only connection to the case was Sabol's injection in Florida, and that the Court therefore lacks jurisdiction over it. Bracco also incorporates the arguments made by Bayer that Sabol's claims are preempted and were not foreseeable.

II. LEGAL STANDARDS

A. PERSONAL JURISDICTION

Defendants GEHC and Bracco urge the Court to dismiss this action for lack of personal jurisdiction. Upon motion, the Court must dismiss an action against any defendant over which it lacks personal jurisdiction. See Fed. R. Civ. P. 12(b)(2). To prevail on such a motion, the "plaintiff bears the burden of showing that the court has jurisdiction over the defendant." In re Magnetic Audiotape Antitrust Litig., 334 F.3d 204, 206 (2d Cir. 2003) (per curiam). Where, as here, the court does not conduct an evidentiary hearing on the issue of personal jurisdiction, "the plaintiff need only make a prima facie showing that the court possesses personal jurisdiction over the defendant." DiStefano v. Carozzi N. Am., Inc., 286 F.3d 81, 84 (2d Cir. 2001) (quoting Bank Brussels Lambert v. Fiddler Gonzalez & Rodriguez, 171 F.3d 779, 784 (2d Cir. 1999)).

When evaluating a motion to dismiss for lack of personal jurisdiction, courts "may consider materials outside the pleadings, including affidavits and other written materials." Jonas v. Estate of Leven, 116 F. Supp. 3d 314, 323 (S.D.N.Y. 2015). Pleadings and affidavits must be viewed in the light most favorable to the plaintiff, with all doubts resolved in its favor. See, e.g., DiStefano, 286 F.3d at 84; Whitaker v. Am. Telecasting, Inc., 261 F.3d 196, 208 (2d Cir. 2001). "However, conclusory allegations are not enough to establish personal jurisdiction." Gmurzynska v. Hutton, 257 F. Supp. 2d 621, 625 (S.D.N.Y. 2003) (internal quotation marks omitted), aff'd, 355 F.3d 206 (2d Cir. 2004); accord Yellow Page Sols., Inc. v. Bell Atl. Yellow Pages Co., No. 00 Civ. 5663, 2001 WL 1468168, at *3 (S.D.N.Y. Nov. 19, 2001) ("The plaintiff cannot rely merely on conclusory statements or allegations; rather, the prima facie showing must be factually supported." (internal citations and quotation marks omitted)).

B. FAILURE TO STATE A CLAIM

Defendants GE Co. and Bayer ask the Court to dismiss this action for failure to state a claim. "To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" Ashcroft v. Iqbal, 556 U.S. 662, 678

(2009) (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007)). This standard is met "when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Id. A complaint should be dismissed if the plaintiff has not offered factual allegations sufficient to render the claims facially plausible. See id. However, a court should not dismiss a complaint for failure to state a claim if the factual allegations sufficiently "raise a right to relief above the speculative level." Twombly, 550 U.S. at 555.

In resolving a Rule 12(b)(6) motion, the Court's task is "to assess the legal feasibility of the complaint, not to assay the weight of the evidence which might be offered in support thereof." In re Initial Pub. Offering Sec. Litig., 383 F. Supp. 2d 566, 574 (S.D.N.Y. 2005) (internal quotation marks omitted), aff'd sub nom. Tenney v. Credit Suisse First Boston Corp., No. 05 Civ. 3430, 2006 WL 1423785 (2d Cir. May 19, 2006); accord In re MF Glob. Holdings Ltd. Sec. Litig., 982 F. Supp. 2d 277, 302 (S.D.N.Y. 2013). District courts are limited to "facts stated in the complaint or in documents attached to the complaint as exhibits or incorporated in the complaint by reference." Kramer v. Time Warner Inc., 937 F.2d 767, 773 (2d Cir. 1991). In this context, the Court must draw

reasonable inferences and resolve any doubts in favor of the non-moving party. See Chambers v. Time Warner, Inc., 282 F.3d 147, 152 (2d Cir. 2002). However, the requirement that a court accept the factual allegations in the claim as true does not extend to legal conclusions. See Iqbal, 556 U.S. at 678.

With respect to preemption, while the overall burden is on "the party asserting that federal law preempts state law," In re Methyl Tertiary Butyl Ether (MTBE) Prods. Liab. Litig., 725 F.3d 65, 96 (2d Cir. 2013) (citing Wyeth v. Levine, 555 U.S. 555, 569 (2009)), prior cases in this District have held that, as an initial matter, the plaintiff must present sufficient factual allegations to show that the manufacturer could unilaterally change its label in accordance with FDA regulations. Utts v. Bristol-Myers Squibb Co., 251 F. Supp. 3d 644, 672 (S.D.N.Y. 2017). The burden then shifts to the defendant to present "clear evidence" that the FDA would have rejected the proposed label change. Id. Finally, a "district court may find a claim preempted only if the facts alleged in the complaint do not plausibly give rise to a claim that is not preempted." Id. (quoting Galper v. JP Morgan Chase Bank, N.A., 802 F.3d 437, 444 (2d Cir. 2015)).

C. VENUE

Defendant Bayer argues that the Court should dismiss this action for improper venue. When a defendant makes an objection to venue, the burden is on the plaintiff to establish that venue is proper. Bank of Am., N.A. v. Wilmington Tr. FSB, 943 F. Supp. 2d 417, 421 (S.D.N.Y. 2013). Pursuant to the federal venue statute, civil actions may be properly brought in:

> (1) a judicial district in which any defendant resides, if all defendants are residents of the State in which the district is located;
> (2) a judicial district in which a substantial part of the events or omissions giving rise to the claim occurred, or a substantial part of property that is the subject of the action is situated; or
> (3) if there is no district in which an action may otherwise be brought as provided in this section, any judicial district in which any defendant is subject to the court's personal jurisdiction with respect to such action.

28 U.S.C. § 1391(b). The statute further defines "residency" for venue purposes, in relevant part, as being satisfied where the defendant entity "is subject to the court's personal jurisdiction with respect to the civil action in question." 28 U.S.C. § 1391(c)(2).

III. ANALYSIS

A. PERSONAL JURISDICTION -- GEHC AND BRACCO

Defendants GEHC and Bracco contest the Court's exercise of personal jurisdiction over them while Sabol contends that the Court may exercise specific jurisdiction over both. For

the reasons that follow, the Court finds that it does not have personal jurisdiction over either GEHC or Bracco and will therefore grant both of their motions.

In diversity cases, the Court analyzes whether it may exercise personal jurisdiction over a defendant using a two-step analysis. First, the Court "must determine whether the plaintiff has shown that the defendant is amenable to service of process under the forum state's laws." Metro. Life Ins. Co. v. Robertson-Ceco Corp., 84 F.3d 560, 567 (2d Cir. 1996). The relevant statute here is the New York long-arm statute. See N.Y.C.P.L.R. § 302. "[S]econd, [the Court] must assess whether [its] assertion of jurisdiction under these laws comports with the requirements of due process." Metro. Life Ins. Co., 84 F.3d at 567.

Sabol does not indicate, either in the Amended Complaint or elsewhere, which section of the New York long-arm statute establishes personal jurisdiction over Bracco and GEHC. The letters submitted by Sabol merely repeat the allegation in the Amended Complaint, applied identically to both Bracco and GEHC, that the Court "has personal jurisdiction . . . under the doctrine of specific jurisdiction" because each of these defendants "purposefully availed itself of the benefits and protections of this state's laws, and Plaintiff's claim

arises out of Defendant[s'] forum-related activities." (Amended Complaint ¶¶ 33, 35.) Sabol further alleges that Bracco and GEHC "actively marketed and caused to be distributed" their gadolinium products "to hospitals and radiological facilities in the State of New York throughout the entire time period in question." (Amended Complaint ¶¶ 33, 35.) Sabol also states that she "was a resident of New York for the majority of the GBCA administrations at issue in th[e Amended] Complaint." (Amended Complaint ¶ 13.) Finally, Sabol alleges, with respect to GEHC, that GEHC owns a facility in New York and is a wholly owned subsidiary of GE Co., a New York company. (September 13 Letter at 2.)

Even considering Sabol need only make out a prima facie showing of personal jurisdiction, these allegations are not sufficient. Sabol received one injection of Bracco's MultiHance product in October 2014, in Florida, and three injections of GEHC's Omniscan product in late November 2008, also in Florida. (Amended Complaint ¶ 2.) Sabol ostensibly relies upon New York Civil Practice Law and Rule ("C.P.L.R.") § 302(a)(3), which covers torts committed outside the state "causing injury to person or property within the state." But regardless of which section of the New York long-arm statute would apply, specific jurisdiction requires that her suit

arise out of, or relate to, the defendant's contacts with the forum. In re Terrorist Attacks on Sept. 11, 2001, 714 F.3d 659, 673-74 (2d Cir. 2013). Sabol's suit, with respect to Bracco and GEHC, does not. Even crediting Sabol's allegations regarding Bracco's and GEHC's marketing and distributing of their products in New York, she does not even attempt to show that these defendants' activities in New York have any relation to the injuries she allegedly received in Florida. Nor does the fact that she lived in New York at the time of other injections establish any connection between the injuries in Florida and Bracco or GEHC. See Brown v. Web.com Grp., Inc., 57 F. Supp. 3d 345, 356 (S.D.N.Y. 2014) (under "situs-of-injury test," courts determine the location of the "original event," and the "injured party's domicile or residence in New York cannot, alone, establish jurisdiction" (internal quotation marks omitted)).

Sabol's allegations specific to GEHC fare no better. GEHC's ownership of a facility in Troy, New York does not establish personal jurisdiction because Sabol does not allege any connection between GEHC's property and the claimed injury, such that C.P.L.R. Section 302(a)(4) would permit the exercise of personal jurisdiction. See Aluminal Indus., Inc. v. Newtown Commercial Assocs., 89 F.R.D. 326, 329 (S.D.N.Y.

1980) ("CPLR § 302(a)(4) is confined to actions arising from the ownership, use or possession of real property; the statute does not make ownership, use or possession of real property per se a basis of jurisdiction."); see also A.W.L.I. Grp., Inc. v. Amber Freight Shipping Lines, 828 F. Supp. 2d 557, 574 (E.D.N.Y. 2011).

While it is a closer call, the Court finds that GEHC's status as a wholly owned subsidiary of GE Co., a New York company, is also insufficient. Sabol does not clearly argue anywhere that GEHC is subject to the Court's *general* jurisdiction.[4] And even if the Court were to glean this argument from between the lines of Sabol's letter exchanges with GE, the Court would reject it for two reasons. First, while it is not uncommon to seek personal jurisdiction over a foreign parent based on the actions of its domestic subsidiary,[5] it is far less common to do the reverse and seek personal jurisdiction over a foreign subsidiary based on the actions of its domestic parent. While some older cases from this district take the position that it is possible to impute

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[4] Sabol does not allege anywhere that either GEHC or Bracco are so heavily engaged in activity in New York such that they are essentially at home in the state, and GEHC and Bracco each note that they are not headquartered or incorporated in New York. (GE September 11 Letter at 1-2; Bracco September 10 Letter at 1-2.) Sabol does not counter these arguments and thus has conceded the point, at least with respect to Bracco. In any event, the Court agrees that it may not exercise general jurisdiction over Bracco and, for the reasons described infra, over GEHC.

[5] E.g., Pfizer Inc. v. Perrigo Co., 903 F. Supp. 14, 16 (S.D.N.Y. 1995).

jurisdiction from a parent to a subsidiary,[6] more recent cases have disagreed,[7] and Sabol provides no explanation or argument for why the Court should adopt the former position in this case.

A bigger obstacle to asserting jurisdiction over GEHC based on its parent's status as a New York company pertains to the type of personal jurisdiction at issue. Sabol seems to be asking the Court to exercise *general* jurisdiction over GE Co., and following the Supreme Court's decision in Daimler AG v. Bauman, it is not entirely clear that courts may impute general jurisdiction from a domestic entity to a foreign entity, regardless of which is the parent and which is the subsidiary. See 571 U.S. 117 (2014). In Daimler, the Supreme Court cautioned that agency relationships may not affect the general jurisdiction analysis. 571 U.S. at 135 n.13 ("Agency relationships, we have recognized, may be relevant to the existence of *specific* jurisdiction. . . . It does not inevitably follow, however, that similar reasoning applies to *general* jurisdiction.").

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[6] Palmieri v. Estefan, 793 F. Supp. 1182, 1193 (S.D.N.Y. 1992) (collecting cases where general jurisdiction was imputed to foreign subsidiary).

[7] See Holland v. Fahnestock & Co., 01 Civ. 2462, 2003 WL 21697880, at *4 (S.D.N.Y. July 21, 2003) ("[U]nder New York law, the acts of a principal cannot subject its agent to jurisdiction."); Sargent v. Budget Rent-A-Car Corp., 94 Civ. 9215, 1996 WL 413725, at *3 (S.D.N.Y. July 24, 1996) (acts of a principal cannot be imputed to foreign agent to confer jurisdiction).

Even where post-Daimler courts have accepted that imputing general jurisdiction to a foreign entity is possible under an agency theory, the complaint must assert more than just the relationship between the two entities -- as has long been required in cases imputing specific jurisdiction to a foreign entity. Ranza v. Nike, Inc., 793 F.3d 1059, 1071-73 (9th Cir. 2015) ("We hold the alter ego test may be used to extend [general] personal jurisdiction to a foreign parent *or* subsidiary when, in actuality, the foreign entity is not really separate from its domestic affiliate."); see also, e.g., Tansey v. Cochlear Ltd., 13-cv-4628, 2014 WL 4829453, at *4 (E.D.N.Y. Sept. 26, 2014) ("The presence of a wholly owned subsidiary in New York is normally an insufficient basis for establishing jurisdiction. . . . Only if grounds exist for piercing the corporate veil can the presence of a subsidiary be used as the basis for jurisdiction over a parent company." (internal quotation marks omitted)). Sabol offers nothing but the ownership of GEHC by GE Co., and this is not enough. See Williamson ex rel. At Home Bondholders' Liquidating Tr. v. Verizon Commc'ns Inc., No. 11 Civ. 4948, 2013 WL 227691, at *1 (S.D.N.Y. Jan. 22, 2013) ("[C]ommon ownership[] is essential to an assertion of jurisdiction, [but] it is not enough on its own to establish

jurisdiction."); Audiovisual Publishers, Inc. v. Manor Care, Inc., No. 04-CV-98, 2006 WL 3511345, at *6 (W.D.N.Y. Dec. 5, 2006) ("[T]he presence of a subsidiary in New York will not, by itself, establish the parent's presence for the purpose of personal jurisdiction in that state.").

The Amended Complaint cannot overcome these two obstacles to asserting jurisdiction over GEHC under the New York long-arm statute. And because the allegations in the Amended Complaint and related briefing also do not establish a prima facie case for the Court's exercise of personal jurisdiction over Bracco under the New York long-arm statute, the Court need not determine whether the exercise of personal jurisdiction over either defendant would comport with the Due Process Clause. See Eades v. Kennedy, PC Law Offices, 799 F.3d 161, 168-69 (2d Cir. 2015). Accordingly, the Court will dismiss the claims against GEHC and Bracco and deny Sabol's request for jurisdictional discovery as to both defendants.[8] See Frontera Res. Azer. Corp. v. State Oil Co. of Azer. Republic, 582 F.3d 393, 401 (2d Cir. 2009) (noting that a

[8] The Court is mindful that jurisdictional discovery may shed light on the relationship between GE Co. and GEHC, which could in turn have an impact on the Court's jurisdictional analysis. Nevertheless, such discovery would be futile. As discussed more fully below, Sabol's Amended Complaint fails to state a claim. See infra note 12; SPV Osus Ltd. v. UniCredit Bank Austria, No. 18-cv-3497, 2019 WL 1438163, at *13 (S.D.N.Y. Mar. 30, 2019) (denying jurisdictional discovery as futile because claims were "fatally deficient on independent grounds").

district court possesses "wide latitude" and "typically [acts] within its discretion to deny jurisdictional discovery when the plaintiff has not made out a prima facie case for jurisdiction" (brackets and internal quotation marks omitted)).[9]

B. FAILURE TO STATE A CLAIM -- GE CO. AND BAYER[10]

Defendants GE Co. and Bayer both argue that the Amended Complaint fails to state a claim. For the reasons that follow, the Court grants both motions.

1. GE Co.

The Amended Complaint fails to state a claim against GE Co. because it does not allege any facts indicating that GE Co. is liable for claims against GEHC. As an initial matter, the Amended Complaint does not differentiate between the two entities; the Court takes judicial notice of the fact that Omniscan is manufactured by GEHC. See Omniscan,

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[9] Sabol briefly argues that the Court may exercise personal jurisdiction over GEHC and Bracco because she was required to join both defendants under Fed. R. Civ. P. 19(a)(1)(A). This argument fails because Fed. R. Civ. P. 19(a)(1)(A) is, by its own words, limited to persons "subject to service of process," and does not circumvent or overcome the requirement that the Court have personal jurisdiction over the defendants. Instead, if the court determines that it cannot exercise personal jurisdiction over an indispensable party, it must determine whether to dismiss the entire action. See Fed. R. Civ. P. 19(b); Broker Genius, Inc. v. Seat Scouts LLC, No. 17-cv-8627, 2019 WL 4054003, at *7 (S.D.N.Y. Aug. 27, 2019). Because the Court dismisses the action for lack of personal jurisdiction and on other grounds, it need not address this issue further.

[10] Because the Court dismisses the allegations against Bracco for lack of personal jurisdiction, it need not address Bracco's arguments that the Amended Complaint fails to state a claim, which, in any event, mirror the arguments made by the Bayer and GE defendants.

https://www.gehealthcare.com/products/contrast-media/omniscan (last visited January 15, 2020); Fed. R. Evid. 201(b)(2).[11]

Just as the Court may not exercise personal jurisdiction over GEHC by reason of its status as a subsidiary of GE Co., neither can it infer liability on the part of GE Co. for GEHC's acts and omissions. Sabol argues that an allegation relying on "a veil-piercing theory is unsuited for resolution on a pre-answer, pre-discovery motion to dismiss." (September 13 Letter at 2.) But even the case on which Sabol relies states that it is not sufficient to "make conclusory allegations of control." City of Almaty v. Ablyazov, 278 F. Supp. 3d 776, 799 (S.D.N.Y. 2017) (quoting SungChang Interfashion Co., Ltd. v. Stone Mountain Accessories, Inc., No. 12 Civ. 7280, 2013 WL 5366373, at *11 (S.D.N.Y. Sept. 25, 2013)). Instead, Sabol must "set[] forth some examples of alleged domination" to survive a motion to dismiss. Id. (quoting SungChang, 2013 WL 5366373, at *11). Sabol provides nothing beyond (1) the allegations in the Amended Complaint,

[11] GE briefly argues that the Amended Complaint fails to state a claim against GE Co. because Sabol does not make any allegations specific to that entity apart from its "manufacturing, testing, licensing, design, marketing, selling, distributing, and advertising" of Omniscan. (GE July 29 Letter at 2.) The Court notes that as long as the defendant has adequate notice, "[Federal] Rule [of Civil Procedure] 8 does not necessarily require . . . that the complaint separate out claims against individual defendants." Wynder v. McMahon, 360 F.3d 73, 80 (2d Cir. 2004).

applied identically to both GE Co. and GEHC, that both "actively marketed and caused to be distributed Omniscan" in New York, and (2) the allegations in her letter-exchanges that "[i]t is public knowledge that GE[HC] is a wholly owned subsidiary" of GE Co. (September 13 Letter at 2.) These allegations do not come close to demonstrating domination such that GE Co. may be held liable for GEHC's actions or omissions.[12]

For those reasons, the Court dismisses the action as against GE Co.

2. Bayer

Bayer argues that the Amended Complaint fails to state a claim for three reasons. First, Bayer argues that Sabol's claims are preempted by federal law. Second, Bayer argues that Sabol cannot show her alleged injuries were foreseeable. Third, Bayer argues that Sabol's alleged gadolinium retention is not a legally cognizable injury.

The Court turns first to Bayer's preemption argument. Federal statutes and regulations govern "the safety

[12] Even if Sabol could demonstrate that GE Co. were liable for the claims against GEHC, the Court would dismiss her claims as preempted for the same reasons it dismisses the claims against Bayer. See infra Section III.B.2. Indeed, the evidence marshaled by Sabol applies with even less force to GE Co. and GEHC, given that Sabol's last injection of Omniscan occurred in 2008, long before the publication of much of the research cited in the Amended Complaint. The Court therefore denies Sabol's request for discovery with respect to her claims against GE Co. See Frontera Res. Azer. Corp., 582 F.3d at 401.

information that appears on the labels of prescription drugs that are marketed in the United States." Merck Sharp & Dohme Corp. v. Albrecht, 139 S. Ct. 1668, 1672 (2019). Following approval of a prescription drug, drug manufacturers may unilaterally alter prescription drug labels without prior FDA approval under the Changes Being Effected ("CBE") regulation. 21 C.F.R. § 314.70(c)(6)(iii)(A). Alterations are permitted under the CBE regulation "to reflect newly acquired information" if the changes "add or strengthen a contraindication, warning, precaution, or adverse reaction for which the evidence of a causal association satisfies the standard for inclusion in the labeling under § 201.57(c)." Id. The newly acquired information must provide "reasonable evidence of a causal association" of a "clinically significant adverse reaction[]" to a drug. Id. § 201.57(c)(6)(i); Utts, 251 F. Supp. 3d at 659 ("[T]he CBE regulation requires that there be sufficient evidence of a causal association between the drug and the information sought to be added."). A clinically significant adverse reaction includes those that are "potentially fatal," "serious even if infrequent," or those that can "be prevented or mitigated through appropriate use of the drug." 21 C.F.R. § 201.57(c)(6)(i), and has a "significant impact on

therapeutic decision-making." 71 Fed. Reg. 3922-01, 3946 (Jan. 24, 2006). These limitations serve to "exclude '[e]xaggeration of risk, or inclusion of speculative or hypothetical risks,' that 'could discourage appropriate use of a beneficial drug.'" Albrecht, 139 S. Ct. at 1673 (quoting 73 Fed. Reg. 2848, 2851 (2008)).

The burden is on Bayer to show that it is impossible to comply with the federal regulatory scheme and state warning requirements. Wyeth v. Levine, 555 U.S. 555, 573 (2009). Thus, to state a claim for failure-to-warn that is not preempted, Sabol must plead a labeling deficiency that Bayer could have corrected under CBE. Utts, 251 F. Supp. 3d at 661. Bayer must (1) demonstrate that Sabol fails to allege facts showing that it could have unilaterally changed Magnevist's label under CBE, or (2) present clear evidence that the FDA would not have approved a change to the drug's label. See Wyeth, 555 U.S. at 568-573.

Bayer argues that based on the allegations in the Amended Complaint, it could not have unilaterally changed Magnevist's label under the CBE regulation because it had no newly acquired information regarding a causal association between Magnevist and a clinically significant adverse reaction in patients with normal renal function. The Court agrees.

Sabol's claims boil down to the simple argument that Bayer should have changed the labels on Magnevist because it had notice that gadolinium retention can have severe adverse effects in patients with normal renal function. But that evidence is simply not there, at least not before Sabol received her last Magnevist injection in 2015. There is no present-day dispute that -- as the FDA recognized in 2018 -- patients with normal renal function may retain gadolinium. But even the FDA's notice advised that "[g]adolinium retention has not been directly linked to adverse health effects in patients with normal kidney function." (Amended Complaint Ex. B at 1.) The FDA noted that although it had "received reports of adverse events involving multiple organ systems in patients with normal kidney function[, a] causal connection between these adverse events and gadolinium retention could not be established." (Id. at 2.) Sabol offers no persuasive reason why the Court should ignore this finding by the FDA and hold that Bayer should have changed the label before 2015 regardless.

Turning to the Amended Complaint, the Court finds that Sabol makes only conclusory allegations that gadolinium retention can cause the kind of debilitating symptoms she has suffered, such as fibrosis. Where conclusory allegations are

"contradicted by a document attached to the complaint, the document controls and the allegation is not accepted as true." Amidax Trading Grp. V. S.W.I.F.T. SCRL, 671 F.3d 140, 146-57 (2d Cir. 2011). Because the FDA's 2018 notice, attached to the Amended Complaint, directly contradicts Sabol's conclusory allegations, the Court need not accept these allegations as true. (Amended Complaint Ex. B at 2 ("[A] causal connection between these adverse events and gadolinium retention could not be established.").) But even aside from the FDA's 2018 notice, the conclusory nature of the allegations renders them fatally deficient under Twombly and Iqbal. Sabol writes that "[p]athologic and/or clinical consequences such as skin changes have been reported in patients with normal renal function," but does not allege facts tending to show that such consequences -- which are only vaguely described -- result from gadolinium. (Amended Complaint ¶ 54(g).) Her allegation that "[a]dverse events involving multiple organ systems have been reported in patients with normal renal function" is also too vague to state a claim and, in any event, does not draw the crucial causal link between those adverse events and the gadolinium retention in patients with normal renal function. (Amended Complaint ¶ 54(h).) So is Sabol's statement that adverse event

reports for NSF-like "symptoms in people with normal renal function were and continue to be reported in significant numbers." (Amended Complaint ¶ 86.)

Sabol is not expected to have all the facts at this stage, of course, and, as a legal matter, even uncommon issues justify changing the label under the CBE regulation. 21 C.F.R. § 201.57(c)(6)(i). But the studies Sabol cites do not provide "reasonable evidence" of a causal relationship between gadolinium retention and adverse events in patients with normal renal function. Wyeth, 555 U.S. at 571. Looking only at the two studies that were published in 2015 or earlier[13] and involved patients with normal renal function, the Court finds that these studies do not amount to such "reasonable evidence." Of course, "issues of fact, credibility, and the weight of the evidence" -- including how much weight should be accorded to publications and other scientific evidence -- are not properly considered on a motion to dismiss. Kardovich v. Pfizer, Inc., 97 F. Supp. 3d 131, 140 (E.D.N.Y. 2015). Nevertheless, where scientific studies are cited and thus incorporated into the complaint, and where those studies

[13] The Court will disregard the many articles cited in the Amended Complaint that were published *after* Sabol's last Magnevist injection in 2015. These studies can have no bearing on her failure-to-warn claim. McGrath v. Bayer HealthCare Pharms. Inc., 393 F. Supp. 3d 161, 168 (E.D.N.Y. 2019).

simply do not support the allegations, the Court may find that the "deficiencies . . . go to the very heart of the plausibility standard under Iqbal." Id. at 140-41. That is precisely the case here.

Turning to the first of the two studies discussed in the Amended Complaint, this study, from March 2015, examined a population of "patients without kidney disease," and focused on "gadolinium-associated skin plaques." (Amended Complaint ¶ 54(u).) Sabol does not even allege, much less plausibly allege, that skin plaques are a "clinically significant adverse reaction" that is serious enough to trigger the CBE regulation. As discussed above, the CBE regulation covers adverse reactions that would "have significant impact on therapeutic decision-making," 71 Fed. Reg. at 3946, such as those that are "potentially fatal" or "serious even if infrequent." 21 C.F.R. § 201.57(c)(6)(i). Without any suggestion that the possibility of skin plaques would have a "significant impact" on a medical professional's decision to use Magnevist, the Court cannot make this jump in logic. Furthermore, the study in question was a case study (as opposed to a controlled study) that involved two patients. Although the Amended Complaint characterizes it as a study of "patients without kidney disease" (Amended Complaint ¶

54(u)), one of the two patients did in fact have renal disease, and, as for the other patient, the study's authors noted the possibility that he "could have had transient renal dysfunction at the time of gadodiamide administration." Robert M. Gathings et al., Gadolinium-Associated Plaques: A New, Distinctive Clinical Entity, 151 JAMA Dermatology 316, 319 (Mar. 2015). The Court is mindful that inferences must be drawn in favor of Sabol's Amended Complaint, but given the limits of the study and its conclusions, the Court can discern no grounds from which to draw an inference that this study could constitute reasonable evidence of a causal relationship between Magnevist and a clinically significant adverse reaction such that the conditions of the CBE regulation are satisfied.

The second study, from 2014, studied "patients with normal renal function" and "found that the brain had hyperintense signals in critical areas." (Amended Complaint ¶ 92.) It is not clear what relationship, causal or otherwise, this study drew between the "hyperintense signals" and the retained gadolinium. The study itself cautions that "[t]he high signal intensity . . . *may* be due to gadolinium deposition in the brain independent of renal function." Tomonori Kanda et al., High Signal Intensity in the Dentate

Nucleus and Globus Pallidus on Unenhanced T1-Weighted MR Images: Relationship with Increasing Cumulative Dose of a Gadolinium-Based Contrast Material, 270 Neuroradiology 834, 839 (Mar. 2014) (emphasis added). It is also not clear, as with the skin plaques, whether "hyperintense signals" constitute a "clinically significant adverse reaction" that would trigger the CBE regulation, or whether such signals are merely a condition; a recent similar case from the Eastern District of New York found that the same study was evidence merely of retention and not the risks of retention. McGrath v. Bayer HealthCare Pharms. Inc., 393 F. Supp. 3d 161, 168 (E.D.N.Y. 2019); Second Am. Compl. ¶ 70, Dkt. No. 86, McGrath v. Bayer HealthCare Pharms. Inc., 393 F. Supp. 3d 161 (E.D.N.Y. 2019) (18-cv-2134). Separately, the Court notes that this study, like the study of skin plaques, was an observational study as opposed to a controlled study, and that "[c]ausal attribution based on case studies must be regarded with caution." McClain v. Metabolife Int'l, Inc., 401 F.3d 1233, 1253 (11th Cir. 2005) (quoting Mary Sue Henifin et al., "Reference Guide on Medical Testimony," Reference Manual on Scientific Evidence 439, 475 (Fed. Judicial Center, 2d ed. 2000)) (discussing the utility of case reports in determining causation in the Daubert context). While federal

regulations define "newly acquired information" to include items such as adverse event reports, 21 C.F.R. § 314.3(b), the CBE regulation still requires causation. And while observational studies such as case studies may be relevant or even probative of causation, see Albrecht, 139 S. Ct. at 1674, the authors here draw only a tentative, at best, suggestion of a causal relationship between the brain signals and the gadolinium retention. In short, neither this study nor the 2015 study supports the inference that gadolinium retention causes a clinically significant adverse reaction that would require a manufacturer to change its label.

Sabol's other evidence is no more persuasive. Several of the pre-2015 publications are studies of rats. As McGrath recently held, such studies are not sufficient to demonstrate that a risk to humans is "apparent." 393 F. Supp. 3d at 170; see generally Albrecht, 139 S. Ct. at 1677. Many other publications cited in the Amended Complaint are studies that simply demonstrate the potential ill effects of gadolinium retention in general. These effects are not disputed; the question is whether Bayer should have known that individuals with normal renal function were at risk. Studies about the harm gadolinium can cause *in general* therefore do not advance her arguments. (Amended Complaint ¶¶ 54, 75-87.)

Nor are Sabol's allegations sufficiently supported by studies that demonstrate mere retention in patients with normal renal function without linking that retention to any adverse events. (Amended Complaint ¶¶ 91-94.) Sabol cites to numerous publications indicating that gadolinium can be retained by patients with normal kidney function -- but that is not enough without "reasonable evidence of a causal association" of a "clinically significant adverse reaction[]" to a drug. 21 C.F.R. § 201.57(c)(6)(i). Sabol does not pursue the argument that gadolinium retention is, on its own, a cognizable injury.[14] Indeed, her alleged injuries are far more severe than mere retention, and her suit centers on Defendants' failure to warn her about "the consequences," "the serious health risks," and the "related injuries" of

[14] Although Sabol writes that the question of "[w]hether gadolinium retention is an injury itself or mere exposure to a toxic substance cannot be resolved on the pleadings," her argument that the Amended Complaint states a cognizable injury is founded on her allegations that she was "physically, mentally, and economically damaged" by Bayer. (September 4 Letter at 3 (citing Pierik v. GE Healthcare, No. 18-cv-7733, 2019 WL 4686551, at *2 (N.D. Ill. June 18, 2019)).) The Court notes that other district courts have differed on whether gadolinium retention by itself is a cognizable injury at the motion to dismiss stage. Compare Goodell v. Bayer Healthcare Pharms. Inc., No. 18-cv-10694, 2019 WL 4771136, at *5 (D. Mass. Sept. 30, 2019) ("Whether the gadolinium retention creates a 'reasonable probability' of future injury is a fact-intensive inquiry not appropriate for resolution on the pleadings."), with Klein v. Bayer Healthcare Pharms. Inc., No. 18-cv-1424, 2019 WL 3945652, at *5 (D. Nev. Aug. 21, 2019) ("[Plaintiff] does not allege facts showing that gadolinium retention is in itself a clinically significant adverse reaction."). Bayer argues that under New York law, mere exposure to a product is not a cognizable injury. (Bayer August 30 Letter at 3 (citing Caronia v. Philip Morris USA, Inc., 5 N.E.3d 11, 14, 19-20 (N.Y. 2013)).) The Court need not address the matter because Sabol herself does not contest that gadolinium retention is a cognizable injury.

gadolinium retention. (Amended Complaint ¶¶ 57-59.) Studies such as those cited in the Amended Complaint about the "*fact* of gadolinium retention," as opposed to the harmful effects of that retention, are thus also unhelpful. McGrath, 393 F. Supp. 3d at 169.[15]

In sum, Sabol does not sufficiently plead that as of 2015 Bayer had reasonable evidence of a causal association between Magnevist and a clinically significant adverse reaction in patients with normal kidney function. Thus, Sabol does not plead facts showing that Bayer had or should have had newly acquired information permitting it to unilaterally add her claimed warning under the CBE regulation. Consequently, Sabol's claims against Bayer are preempted, and because the Court finds that the Amended Complaint does not sufficiently allege a causal association between Sabol's Magnevist injections and the injuries she suffered, it need not address Bayer's arguments regarding foreseeability and causation.

C. VENUE -- BAYER

[15] For example, the Amended Complaint alleges that "[s]ome patients sent letters to the FDA as early as 2012, warning" that gadolinium retention was occurring in patients with normal renal function. (Amended Complaint ¶ 91.) Sabol also discusses a 2015 study of the autopsies of thirteen patients who had "normal or near normal renal function" and were found to have retained gadolinium in their brains. (Amended Complaint ¶ 94.)

Because the Court grants Bayer's motion on other grounds, it will deny as moot Bayer's motion to dismiss for improper venue. Nevertheless, the Court notes that venue is proper in the Southern District of New York as to Sabol's claims against Bayer. While the Amended Complaint does not, on its own, provide sufficient detail regarding Sabol's injections for the Court to infer that venue is proper in the Southern District, the September 4 Letter states that "[t]he majority of the gadolinium administrations at issue in this lawsuit (at least 14 out of 23) occurred in the Southern District [of] New York (e.g., Mount Sinai Medical Center in the Upper East Side in the New York City borough of Manhattan) . . . ." (September 4 Letter at 1.) At this stage of the proceeding, the September 4 Letter provides sufficient support for the Court to find that "a substantial part of the events or omissions giving rise to the claim occurred" in the Southern District of New York. 28 U.S.C. § 1391(b)(2); see Caremark Therapeutic Servs. v. Leavitt, 405 F. Supp. 2d 454, 457 (S.D.N.Y. 2005) ("[C]ourts may consider materials outside the pleadings on a motion to dismiss for improper venue."). Venue is thus proper under 28 U.S.C. § 1391(b)(2).[16]

[16] The Court also notes that the remaining defendants do not contest the appropriateness of venue. This Court is Sabol's third venue -- the action was first filed in the Northern District of California before being transferred to the Middle District of Florida. Normally, if venue is

IV. ORDER

Accordingly, it is hereby

ORDERED that the motion so deemed by the Court as filed by Defendants Bayer HealthCare Pharmaceuticals, Inc., Bayer Corporation, and Bayer Healthcare LLC to dismiss (Dkt. Nos. 44, 57, and 65) the Amended Complaint of plaintiff Marcia Sabol ("Amended Complaint," Dkt. No. 64) pursuant to Rules 12(b)(6) and 12(b)(3) of the Federal Rules of Civil Procedure is **GRANTED**; and it is further

ORDERED that the motion so deemed by the Court as filed by Defendant Bracco Diagnostics, Inc. to dismiss (Dkt. Nos. 68) the Amended Complaint pursuant to Rule 12(b)(2) of the Federal Rules of Civil Procedure is **GRANTED**; and it is further

ORDERED that the motion so deemed by the Court as filed by Defendants GE Healthcare Inc. and General Electric Company to dismiss (Dkt. Nos. 68) the Amended Complaint pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure is **GRANTED**.

SO ORDERED.

Dated: New York, New York
12 February 2020

Victor Marrero
U.S.D.J.

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proper as to some defendants and not others, the district court has "wide discretion" to transfer the entire case to a forum proper for all defendants, sever the case and transfer only the portion of the case against the defendants for whom venue is improper, or dismiss the action as to the defendants for whom venue is improper. 14 Charles Alan Wright & Arthur R. Miller, Federal Practice and Procedure § 3827 (2019). But because the remaining defendants have waived any challenge to venue, see Tri-State Employment Servs., Inc. v. Mountbatten Sur. Co., Inc., 295 F.3d 256, 260 n.2 (2d Cir. 2002), and because, in any event, the Court dismisses the action as to the other defendants on different grounds, supra, it is not necessary to determine whether venue is proper as to those defendants.